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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/628,464	07/29/2003	Jon Elliot Adler	100337/54260US	4703
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CROWELL & MORING LLP INTELLECTUAL PROPERTY GROUP P.O. BOX 14300 WASHINGTON, DC 20044-4300			HOWARD, ZACHARY C	
			ART UNIT	PAPER NUMBER
			1646	
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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/628,464	ADLER ET AL.
	Examiner Zachary C. Howard	Art Unit 1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 08 November 2005.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 68-92 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 68-92 is/are rejected.
- 7) Claim(s) 68 and 71 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____.
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: _____.

## **DETAILED ACTION**

### ***Status of Application, Amendments and/or Claims***

The amendment of 9/30/05 has been entered in full. Claims 1-67 are canceled. New claims 68-92 are added.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 68-92 are under consideration in the instant application.

### ***Withdrawn Objections and/or Rejections***

The following page numbers refer to the previous Office Action (3/30/05).

The objection to the specification at pg 3 is *withdrawn* in view of Applicants' amendments to paragraph 33.

All rejections of claims 1-3 and 16-26 are *withdrawn* in view of Applicants' cancellation of these claims.

It is noted that the previous rejections under 103(a) have not been applied to the new claims in view of further consideration by the examiner.

Please see the new claim objections and rejections, below.

### ***Claim Objections***

Claim 68 is objected to because the word "differing" is misspelled as "differeing" in part (iv).

Claim 71 is objected to because the word "contained" is misspelled as "contaned".

Appropriate correction is required.

***Claim Rejections - 35 USC § 101, utility***

Claims 68-92 are rejected under 35 U.S.C. § 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility. This rejection was set forth at pg 3-6 of the 3/30/05 Office Action for claims 1-3 and 16-26 (now cancelled) and is herewith applied to new claims 68-92.

Applicants' arguments (9/30/05; pg 9-12) as they pertain to the rejection have been fully considered but are not deemed to be persuasive for the following reasons.

In the response dated 9/30/05, Applicants argue that the claimed isolated T2R76-encoding nucleic acid sequence encodes a human bitter taste receptor that one of skill in the art would recognize as having substantial and credible utility. Applicants submit that the specification teaches that the T2R76 nucleic acid encodes a member of the T2R family of proteins that share common characteristics. Applicants submit that a number of references (including a prior art incorporated by reference and recently filed provisional and non-provisional applications) demonstrate that many members of the T2R family encode receptors that respond to bitter taste ligands. Applicants argue that this success provides substantial evidence that the genus of T2R proteins, including T2R76, encode functional bitter taste receptors and that this can be confirmed using the disclosed assay systems. Applicants submit that the specification teaches that cell lines expressing T2R76 can be screened with a set of 6 bitter compounds as a means to confirm that T2R76 is a bitter taste receptor. Applicants submit a 132 Affidavit by Mark J. Zoller that assays conducted with these compounds have confirmed that TRR76 responds specifically to the compound PROP as well as brucine (a bitter alkaloid).

Applicants' arguments have been fully considered but are not found persuasive. The affidavit under 37 CFR 1.132 filed 9/30/05 is insufficient to overcome the rejection of claim 68-92 based upon lack of utility under 35 USC 101 as set forth in the last Office action for the following reasons. The Affidavit

states that PROP and brucine, but not other bitter ligands, specifically activate hTR276 expressed in HEK-293 cells. This activation is stated to result in detectable changes in intracellular calcium changes and the results are stated to be contained in Figure 2 attached to the affidavit. However, there is no Figure 2 attached to the affidavit provided to the Examiner. The evidence in support of utility is not found persuasive because Figure 2 has not provided for independent evaluation by the Examiner. Therefore, the utility rejection is maintained for reasons set forth in the 3/30/05 Office Action. The proposed uses of the claimed invention are starting points for further research and investigation by the skilled artisan to determine potential practical uses of the claimed nucleic acids.

***Claim Rejections - 35 USC § 112, 1<sup>st</sup> paragraph, scope of enablement***

Claims 68-92 are rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention so that it would operate as intended without undue experimentation. This rejection was set forth at pg 7 of the 3/30/05 Office Action for claims 1-3 and 16-26 (now cancelled) and is herewith applied to new claims 68-92.

Applicants' arguments (9/30/05; pg 13-15) as they pertain to the rejection have been fully considered but are not deemed to be persuasive for the following reasons.

In the response dated 9/30/05, Applicants submit that as the claimed invention is supported by a specific and substantial asserted utility, one of skill in the art would know how to use the claimed invention without undue experimentation.

Applicants' arguments have been fully considered but are not found persuasive. For the reasons described above in the section "Claim Rejections – 35 USC § 101", the claimed invention is not supported by a specific and

substantial asserted utility, and therefore it is maintained that one of skill would not know how to use the claimed invention without undue experimentation.

Even if the claimed invention was supported by a specific and substantial asserted utility or a well established utility, the claims would still be rejected under 35 U.S.C. 112, first paragraph. This rejection was set forth previously at pg 7-12 of the 3/30/05 Office Action for claims 1, 2, 16-18 and 20-26 (now cancelled); new claims 68-92 are herewith included in this rejection. It is maintained that the claims lack enablement for the full scope of variant TR76 polypeptides encoded by the nucleic acids encompassed by the claims.

Applicants' arguments (9/30/05; pg 15-16) as they pertain to the rejection have been fully considered but are not deemed to be persuasive for the following reasons.

In the response dated 9/30/05, Applicant submits that the claims have been drafted in a manner commensurate in scope with the specific teachings of the specification. Applicants argue that it would be within the skill in the art to identify those nucleic acids that encode polypeptide that bind to the same bitter ligand that binds a T2R76 polypeptide of SEQ ID NO: 2.

Applicants' arguments have been fully considered but are not found persuasive. Applicants' claims encompass a vast number of T2R76 variants, including fragments of SEQ ID NO: 2 of any size. For example, claim 68, part (i) encompasses nucleic acids encoding polypeptides "having at least 90% sequence identity to the polypeptide contained in SEQ ID NO: 2". First, SEQ ID NO: 2 is an amino acid sequence of 318 amino acids. Therefore, the genus of nucleic acids that are at least 90% similar to SEQ ID NO: 2 includes up to 10% of the sequence changed, or up to 31 amino acids changed anywhere in the sequence of SEQ ID NO: 2. Furthermore, the term "contained in SEQ ID NO: 2" is indefinite and therefore has been interpreted to include any shorter sequence "contained" within the longer SEQ ID NO: 2 (See Rejections under 35 USC 112, 2<sup>nd</sup> paragraph, below). Therefore, claim 68 also encompasses nucleic acids encoding any polypeptide fragment of SEQ ID NO: 2 (as well as polypeptides

that are 90% similar to these fragments). Furthermore, claim 68, part (iii) is drawn to any nucleic acid sequence that hybridizes to SEQ ID NO: 1 under particular stringent conditions. Such hybridizing fragments would include fragments of any size that are complementary to any shorter sequence within the longer sequence of SEQ ID NO: 1. Furthermore, claim 68, part (iv) is drawn to nucleic acids differing "by at least one functionally equivalent codon". This phrase is used in the specification but is not defined and therefore includes codons that code for different amino acids. Therefore, the claims encompass nucleic acids with an unlimited number ("one or more") changes to the encoded protein. The claims do include the limitation that the encoded variant bitter taste receptor binds a bitter ligand that specifically binds to T2R76. However, this functional limitation is not sufficient to enable the vast genus of encompassed variants. First, the fact that a bitter ligand can bind a T2R76 variant does not indicate the said variant is functional such that it can be used as SEQ ID NO: 2. For example, a deletion of the internal portion of the protein that interacts with a G protein would still allow the variant to bind an extracellular ligand but would not activate intracellular cell signaling. In order for a variant to be used, it would need to be functional in an assay in which the ligand activates cell signaling. Second, even if such a functional limitation was included, the genus of encompassed molecules is so large that it would require undue experimentation to test and screen each one for activity.

Therefore it is maintained for the reasons set forth in the previous Office Action (3/30/05) that due to the large quantity of experimentation necessary to generate the large number of variants recited in the claims and possibly screen same for activity, the lack of direction/guidance presented in the specification regarding which structural features are required in order to provide activity, the absence of working examples directed to same, the complex nature of the invention, the state of the prior art which establishes the unpredictability of the effects of mutation on protein structure and function and the difficulties encountered in screening T2Rs, exemplified by Hoon et al., Chandrashekhar et

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al., and Lindemann (cited in the 3/30/05 Office Action), and the breadth of the claims which fail to recite adequate structural or functional limitations, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope should a substantial utility be established for the claimed polynucleotides.

Applicants further submit that the current claims are directed to "isolated" host cells and therefore do not encompass gene therapy. Applicants further argue that the phrase T2R polypeptide (in relation to a co-expressed T2R polypeptide) is not unduly broad in view of the extensive number of cloned T2Rs publicly disclosed prior to filing of the instant application.

Applicants' claim limitations and arguments have been fully considered and are considered persuasive with regard to host cells and co-expressed T2Rs.

***Claim Rejections - 35 USC § 112, 1<sup>st</sup> paragraph, written description***

Claims 68-92 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection was set forth at pg 12-13 of the 3/30/05 Office Action for claims 1, 2, 16-18 and 20-26 (now cancelled); new claims 68-92 are herewith included in this rejection.

Applicants' arguments (9/30/05; pg 16-18) as they pertain to the rejection have been fully considered but are not deemed to be persuasive for the following reasons.

In the response dated 9/30/05, Applicants traverse the rejection "for the same reasons as the § 101 and § 112 enablement rejections" (pg 16). Applicants submit that the specification provides sufficient information to show Applicants were in possession of isolated nucleic acid sequences that encode a human

bitter taste receptor that specifically responds to bitter ligands including PROP in binding assays. Applicants direct the Examiner to Example 5 that constructively reduces to practice the assay methods using bitter ligands including PROP that have later been actually reduced to practice and show that T2R76 is specifically responsive to PROP. Applicants further submit that they were in possession of the genus of sequences encompassed by the claims, because these sequence are highly related structurally and retain the functional properties of the parent polypeptide of SEQ ID NO: 2 (specific binding and responsiveness to SEQ ID NO: 2).

Applicants' arguments have been fully considered but are not found persuasive.

First, as set forth above the evidence (in the form of an affidavit), is not sufficient to demonstrate activation of SEQ ID NO: 2 by PROP (because Figure 2 has not been provided to the Examiner for evaluation). Second, even if this evidence was sufficient to demonstrate activation of SEQ ID NO: 2 by PROP, this functional activity would not be commensurate in scope with the functional limitation recited in the claims. The claims only require "binding" of a ligand to SEQ ID NO: 2, whereas possession of a usable member of the claimed genus requires activation of the receptor. Binding of a ligand to a variant of SEQ ID NO: 2 could occur in the absence of activation. Finally, even if the claims contained a functional limitation related to activation of the receptor, it would not be sufficient to demonstrate possession of the vast genus of polynucleotides encompassed by the instant claims. As set forth in detail above (see the Rejection under 112, 1<sup>st</sup> paragraph, enablement), the genus of claimed polynucleotides comprises polynucleotides encoding polypeptides with an unlimited number of changes to the encoded polypeptide. As set forth previously (3/30/05), although one of skill in the art would reasonably predict that variant sequences exist that retain the functionality of the parent polypeptide, one would not be able make useful predictions as to the nucleotide positions or identities of those sequences based on the information disclosed in the specification.

The instant disclosure of a single polynucleotide, that of SEQ ID NO: 1, encoding a polypeptide with no instantly disclosed specific activities, does not adequately support the scope of the claimed genus, which encompasses a substantial variety of subgenera. A genus claim may be supported by a representative number of species as set forth in Regents of the University of California v Eli Lilly & Co, 119F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus, or of a recitation of structural features common to the genus, which features constitute a substantial portion of the genus. The instant specification discloses, however, a single isolated polynucleotide sequence SEQ ID NO: 1, which is not sufficient to describe the essentially limitless genera encompassed by the claims.

The specification has not provided a particular essential feature, either a functional or structural feature, that the claimed genus of polynucleotides possesses. The recitation of the property of hybridization does not, alone, provide sufficient information regarding the structure of the claimed polynucleotide variants. Further, most of these variants are expected to encode polypeptides having an amino acid sequence different than that of SEQ ID NO: 2 and thus having different structural and functional properties. Similarly, the recitation of a percent identity to SEQ ID NO: 2 provides no description of any amino acid sequence other than that of SEQ ID NO: 2. The specification has not defined what particular common structural or functional properties are possessed by the claimed genus of polynucleotides. Thus one of skill in the art would appreciate that Applicant was not in possession of the claimed genus of polynucleotides at the time of filing.

The instant claims are not directed to that which is disclosed as essential to the invention, i.e. something that is homologous to the parent SEQ ID NO: 1 and has the function of the parent polynucleotide. Thus, with the exception of the polynucleotide of SEQ ID NO: 1, and other polynucleotides which encode a

polypeptide of SEQ ID NO: 2, the skilled artisan cannot envision encompassed variants. Therefore, only a polynucleotides encoding a polypeptide of SEQ ID NO: 2, and polynucleotides consisting of fragments thereof, or polynucleotides consisting of fragments thereof and heterologous sequences (e.g. carrier or tag sequences), but not the full breadth of the claims meet the written description provision of 35 U.S.C. §112, first paragraph.

Claim 92 also lacks written description because the claims encompass T2R nucleic acids of species other than humans, but the specification only provides examples of human T2Rs that are known in the art (page 12). The specification refers to mouse and rat sequences on page 18 but does not provide any specific examples of T2Rs from species other than humans, or how to identify such sequences through structural features. Thus one of skill in the art would appreciate that Applicant was not in possession of the claimed genus of T2R polynucleotides at the time of filing. This issue was raised previously with respect to claim 20 (now cancelled); however, Applicants' response does not address this issue with respect to written description.

***Claim Rejections - 35 USC § 112, 1st paragraph, new matter***

Claims 77-79 and 81-83 are also rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement because the claims contain new matter.

Each of claims 77-79 and 81-83 was newly submitted 11/8/2005.

Claim 77 is directed to retroviral vectors comprising an isolated nucleic acid sequence. However, the specification as originally filed does not teach retroviral vectors. The specification on pg 35-36 discusses expression constructs. Representative promoters are taught to include "long terminal repeat promoter from retrovirus" (pg 36, ¶ 93). Suitable vectors are taught to include "viruses such as vaccinia virus or adenovirus" (pg 36, ¶ 94). However, there is no conception of "retroviral vectors" as a particular species of vector of the claimed invention. Therefore, the specification as originally filed lacks support for the genus of

molecules encompassed by the claim, nor does the concept of the specific genus flow naturally from the disclosure of the specification. Claims 78 and 81-83 depends from claim 77 and therefore include new matter for the same reason.

Claim 79 is directed to isolated nucleic acids operably linked to a regulatable promoter. However, the specification as originally filed lacks support for a genus of regulatable promoters. The specification (pg 46, ¶ 93) discusses “constitutive promoters” and “inducible promoters”. There is no teaching relating to “regulatable promoters”. The genus of “regulatable promoters” includes “inducible promoters” but is broader because it also encompasses promoters that can be repressed (rather than induced). Therefore, the specification as originally filed lacks support for the genus of molecules encompassed by the claim, nor does the concept of the specific genus flow naturally from the disclosure of the specification. Claim 78 depends from claim 77 and therefore includes new matter for the same reason.

Claim 81 is directed to isolated plasmid comprising a T2R76 nucleic acid and a sequence encoding a G protein. However, the specification as originally filed lacks support for a single plasmid comprising these two nucleic acids. Originally filed claim 23 was directed to a host cell comprising a G protein  $\alpha$  subunit capable of coupling to a T2R76 polypeptide. However, this teaching is broader and encompasses host cells with two separate nucleic acids encoding the T2R76 and the G protein. Nowhere in the originally filed claims or specification is the conception of a single nucleic acid molecule comprising the sequence encoding the T2R76 and G protein. Therefore, the specification as originally filed lacks support for the genus of molecules encompassed by the claim, nor does the concept of the specific genus flow naturally from the disclosure of the specification. Claims 82 and 83 depend from claim 81 and therefore include new matter for the same reason.

***Claim Rejections - 35 USC § 112, 2<sup>nd</sup> paragraph***

Claims 68-92 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 68-72 are indefinite because the metes and bounds of the phrase "contained in" are unclear. For example, it is unclear whether a "polypeptide contained in SEQ ID NO: 2" is limited to a polypeptide consisting of SEQ ID NO: 2, or whether it encompasses shorter polypeptides (fragments) that are "contained in" the longer sequence of SEQ ID NO: 2. For purposes of prosecution, this claim has been interpreted broadly to include fragments of SEQ ID NO: 1 or 2.

Claim 70 is indefinite because the metes and bounds of the phrase "a polypeptide having at least 95-99% sequence identity..." are unclear. If this phrase recited "a polypeptide having 95-99% sequence identity..." it would be clear that it encompass a genus limited to 95-99% identity. However inclusion of the phrase "at least" makes it unclear whether or not this genus also includes polypeptides having sequence identity that is greater than 99%. Does a polypeptide that is 99.5% similar meet the definition of "at least 95-99%"?

Claim 77 is indefinite because recites, "The isolated nucleic acid sequence of claim 77 wherein the vector is a retroviral vector." This is indefinite because the claim depends from itself, and because the term "the vector" lacks antecedent basis. For purposes of prosecution, this claim has been interpreted to depend from claim 75. Applicants are also asked to review claim 78 and confirm that it is intended to depend from claim 77.

The remaining claims are rejected for depending from an indefinite claim.

***Claim Rejections - 35 USC § 102***

Claims 68-73 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by WO200257309-A1, Miwa et al, published July 25, 2002. This rejection was set forth at pg 15-16 of the 3/30/05 Office Action for claims 1-3 (now cancelled) and is herewith set forth for new claims 68-73.

Applicants' arguments (9/30/05; pg 19) as they pertain to the rejection have been fully considered but are not deemed to be persuasive for the following reasons.

In the response dated 9/30/05, Applicants submit an Affidavit signed by Robin Teskin that Applicants argue establishes that Applicants were in possession of the claimed isolated hT2R76 sequence prior to the publication date of the Miwa disclosure.

Applicants' arguments have been fully considered but are not found persuasive. The affidavit filed on 9/30/05 under 37 CFR 1.131 has been considered but is ineffective to overcome the Miwa reference. The affidavit is ineffective because it does not meet the requirements of who may make an affidavit or declaration under 37 CFR 1.131. See MPEP 715.04 [R-2], I. WHO MAY MAKE AFFIDAVIT OR DECLARATION, which states,

"The following parties may make an affidavit or declaration under 37 CFR 1.131:

(A) All the inventors of the subject matter claimed.

(B) An affidavit or declaration by less than all named inventors of an application is accepted where it is shown that less than all named inventors of an application invented the subject matter of the claim or claims under rejection. For example, one of two joint inventors is accepted where it is shown that one of the joint inventors is the sole inventor of the claim or claims under rejection.

(C) If a petition under 37 CFR 1.47 was granted or the application was accepted under 37 CFR 1.42 or 1.43, the affidavit or declaration may be signed by the 37 CFR 1.47 applicant or the legal representative, where appropriate.

(D) The assignee or other party in interest when it is not possible to produce the affidavit or declaration of the inventor. Ex parte Foster, 1903 C.D. 213, 105 O.G. 261 (Comm'r Pat. 1903).

Affidavits or declarations to overcome a rejection of a claim or claims must be made by the inventor or inventors of the subject matter of the rejected

claim(s), a party qualified under 37 CFR 1.42, 1.43, or 1.47, or the assignee or other party in interest when it is not possible to produce the affidavit or declaration of the inventor(s). Thus, where all of the named inventors of a pending application are not inventors of every claim of the application, any affidavit under 37 CFR 1.131 could be signed by only the inventor(s) of the subject matter of the rejected claims. Further, where it is shown that a joint inventor is deceased, refuses to sign, or is otherwise unavailable, the signatures of the remaining joint inventors are sufficient. However, the affidavit or declaration, even though signed by fewer than all the joint inventors, must show completion of the invention by all of the joint inventors of the subject matter of the claim(s) under rejection. *In re Carlson*, 79 F.2d 900, 27 USPQ 400 (CCPA 1935).

In the instant case, a petition under 37 CFR 1.47 was not granted, the application was not accepted under 37 CFR 1.42 or 1.43, and there is no indication that it was not possible to produce the affidavit or declaration of the inventor. Therefore, the affidavit signed by Applicants' representative does not meet the requirements of who may submit a declaration under 37 CFR 1.131.

Therefore, the rejection is maintained for the reasons set forth previously (3/30/05). Although claims 1-3 have been cancelled, new claims 68-73 each encompass a polynucleotide as taught by Miwa. Therefore, Miwa clearly anticipates claims 68-73.

### **Conclusion**

No claims are allowed.

Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory

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action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachary C. Howard whose telephone number is 571-272-2877. The examiner can normally be reached on M-F 9:30 AM - 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

zch



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SUPERVISORY PATENT EXAMINER